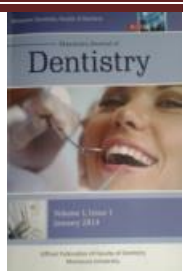
Evaluation of Poly-ether-ether-ketone (PEEK) mandibular two implant retained overdenture on zirconium oxide bar retained with heat cured soft liner



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Abstract:

Purpose: The aim of study was to evaluate the Poly-ether-ether-ketone (PEEK) mandibular overdenture on zirconium oxide (ZrO_2) bar retained with heat cured soft liner regarding the peri-implant soft tissue changes around the fixtures.

Material and methods: Ten completely edentulous patients were chosen for this study (average age from 55-65 with main age 60. A complete denture was constructed and adjusted for insertion and delivery for all patients. On the planned sites in the canine region, CAD-CAM limiting surgical stereolithographic Stent (STL) was fabricated. Implant fixtures have been surgically placed. Zirconium oxide bar was constructed after the osseointegration period. The patients were divided into two groups according to the shape of a zirconium oxide bar:

- Group (I): zirconium oxide bar without cantilever extension.
- Group (II): zirconium oxide bar with cantilever attachment extension.

The master cast was screened with zirconium bar. PEEK overdenture with 1 mm space for heat cured soft liner was constructed. CAM manufacturing of PEEK overdenture was done. Soft liner was incorporated in the surface of the overdenture. The peri-implant soft tissue changes were evaluated by using the following variables (1) gingival index (2) bleeding index (3) probing depth. The measurements were evaluated immediately following mandibular overdenture insertion (T0), six months (T6) and one year (T12) after mandibular overdenture insertion.

- Results: Gingival scores significantly increased with advance of time for group I ($p<.001$) and group II ($p=.015$). Group II showed significant higher gingival scores than group I at T6 ($p=.045$). Bleeding scores significantly increased with advance of time for group II only ($p=.005$). There was no significant difference in bleeding scores between groups at different observation times. Probing depth significantly increased with advance of time for group I ($p<.001$) and group II ($p<.001$). Group II showed significant higher pocket depth than group I at T12 ($p=.021$). No markedly difference in vertical bone loss between T6 and T12 for both groups.

Conclusion:

1- Using PEEK framework over mandibular two implant supported zirconium oxide bar without cantilever and without retaining mechanism of the bar in form of clip or sleeve is considered a promising treatment solution.
2- Using heat cured soft liner in the desired areas beneath the bar maintain good peri-implant results either with or without cantilever extension.

Introduction

Implant-overdentures (IODs) supported by titanium bars improve stability and comfort in edentulous patients being unsatisfied with their complete dentures. Today's computer-assisted design computer-assisted manufacture (CAD-CAM) technology allows for fabrication of titanium bars additionally from zirconium dioxide (ZrO2) [3]. Zirconia (zirconium dioxide, ZrO_2), named also as "ceramic steel", has ideal for dental use: excellent wear properties, biocompatibility, superior toughness, fatigue resistance and strength. Zirconium (Zr) which is a strong metal has similar physical and chemical properties to titanium (Ti) [4]. Generally, zro2 is dull white in color and its opacity can cover the underneath structure. Most dental zirconia systems show structural coloring (dyeing) to upgrade the esthetic [5]. Most importantly, CAD-CAM system has the ability to produce zirconia restorations with sufficient precision for dental use.[6].

Poly-ether-ether-ketone (PEEK) became an important high-performance thermoplastic. It candidates for replacing metal implant components in vertebral surgery as a material of the interbody fusion cage [7]. PEEK was reported as an alternative material framework to base metal alloys when constructing RPDs[8]. Tensile properties and young's modulus are close to human bone, enamel and dentin [9]. PEEK has also been specifically desirable for CAD-CAM framework fabrication in prosthetic dentistry [10].

In several studies it was proposed that resilient denture liner be used as an attachment for bar / implant retained overdentures [11-14]. The resilient liners have various advantages including minimal wear, absorption of occlusal force, load distribution to the implants and patient comfort. [13, 14]. Soft liners have the ability to obturate the spaces in the denture base around the bar, enhance peri-implant tissue health, increase satisfaction of patient, reduce costs and minimize soft tissue complications compared to clip attachments [11]. In addition, these liners are related with diminished maxillary bone resorption, decreased incidence of maxillary flabby ridges and reduced maxillary dentures relining in comparison with clips.[12]

The health of peri-implant tissue is important for implant-retained mandibular overdentures to achieve long-term success. The clinical indicators of peri-implant tissue health and implant survival, such as gingival scores, bleeding values and probing depths are significant indicators. [12]
Limited research is published to evaluate the impact of mandibular implant supported overdentures from PEEK with bar attachment milled from zirconia retained by heat cured soft liner. Therefore, the purpose of this study was to evaluate the PEEK mandibular zirconium oxide bar retained overdenture retained with heat cured soft liner.

Materials and methods

Ten completely edentulous patients were selected from the Out-Patient Clinic of Prosthodontics' Department, Faculty of Dentistry, Mansoura University seeking for prosthetic rehabilitation**.**

The patients selected in this study were according to the following criteria:

- Completely edentulous maxillary and mandibular alveolar ridges covered by healthy mucosa verified by probing test with plastic periodontal probe. The patients were edentulous for at least six months before implant placement with no previous denture experience as obtained from dental history. (figure 1)
- Sufficient bone quantity (bone height was not less than 15 mm, and bone width was not less than 5mm) and bone quality was D3 according to Misch bone density classification scheme (350 to 850 Housefield units) with normal trabecular pattern in the interforaminal area of the mandible to receive standard implants of at least 11.5 mm length and 3.75mm in diameter. Bone quantity and quality were verified by preoperative cone beam computerized tomography (CBCT).
- Class I maxillomandibular relationship as detected by tentative jaw relation.
- Mandibular ridges are with moderate to severe alveolar ridge resorption and not planned for conventional mandibular denture construction.
- Sufficient interarch space (20-23 mm) as verified by tentative jaw relation.
- Sufficient restorative space (10-12 mm) detected for placement of bar attachment by putty index technique.

Exclusion criteria:

- Patients with absolute contraindications for implant placement such as: active cancer, metabolic diseases that directly affect the bone such as advanced and untreated osteoporosis, hyperparathyroidism, autoimmune disease.
- Patients with relative contraindications such as: diabetic patients, patients with history of parafunctional habits (bruxism, clenching), bad habits as heavy smoking and alcoholism, patients with history of periodontitis and pregnancy patients.
- General contraindication for surgical procedures such as patient with head and neck radiotherapy, patients with bleeding disorders, hepatic patients, and patient under cortisone therapy.
- Patients with local bone defects in the areas of canine region.
- TMJ or neuromuscular disorders (by TMJ examination).

All patients in this study were informed about the treatment plan and the frequent calls and visits to follow up and their acceptance to share in this study according to Ethical Committee guidelines, Faculty of Dentistry, Mansoura University. The consents were confirmed and signed up by all patients.

A complete denture was constructed and adjusted for insertion and delivery for all patients. On the planned sites in the canine region, CAD-CAM limiting surgical stereolithographic Stent (STL) was fabricated. Implant fixtures have been surgically placed.

- After 3 months from implant fixture surgical placement, the healing abutment removed by using the prosthetic driver.
- The transfer copies were placed on the two implants by using the prosthetic driver and retain by tightening the screw to implant body.
- Then a hole made in the custom tray of the patients in the site of implants and checked for passive insertion and removal without interference with the transfer copy.
- Border molding with green stick compound and zinc oxide eugenol free impression material adapted in the fitting surface of tray and applied to the patient mouth
- Then light body impression was injected around the transfer copy and in the fitting surface of tray and then the tray adapted in patient mouth and fixation done by using composite
- Once the impression material has set, unscrew the impression coping and remove the impression tray and verify that the impression material is completely adapted around the direct pickup coping.
- Replace the healing abutment immediately to prevent the soft tissue from collapsing.
- Then attach appropriate diameter implant analog to the direct pickup coping in the impression and insert the long coping screw through the access hole in the impression tray by hand tightening and verifying that the coping and analog are properly assembled.
- The master cast with abutment analogues were assembled.
- The mandibular study cast with the Ti-base abutments was then fixed on the scanner table and scanned using 3-D scanner to obtain the standard triangulation (STL) file format which was then imported into CAD software used in this study* to start the designed process.
- The arch is digitally scanned to produce a 3-D virtual model. (Figure 19)

- With the scanning abutments, the location, angulation and connection orientation of each implant are provided.
- Each scanning abutment is physically measured with digital callipers contained in the proprietary software library.
- The denture setup is then scanned and the resulting 3-D image is superimposed over that of the mater model.
- A dental technician with CAD expertise designs the bar in a virtual environment.
- According to the type of bar attachment used, patients were divided into two equal groups as follow:
- **Group I:** patient receiving two implants supported mandibular over-denture without cantilever zirconium oxide bar.
- **Group II:** patient receiving two implant retained mandibular over-denture with cantilever zirconium bar.

For both groups:

- Ovoid cross section design for ZrO2 bar was selected for this study. The Designs are based on one of the standard bar types available in the software library and manipulate every aspect of the bar with a level precision measured. This enable to set the height of the bar off the tissue and to craft the shape of bar for maximum strength, optimal comfort and proper support for the PEEK framework.
- The design file is converted to a file type that can be executed by milling software.
- The milling software runs a preliminary routine that nests the virtual bar within a zirconia block and maps out the proper tool path. (Figure 23)
- Once the tool path has been verified and approved, zirconia block is attached to a milling fixture and placed within the highly precise 5-axis mill.
- For group II the cantilever extension was only 7mm. in length with the same specifications as original bars.
- When the milling process is complete, the bar undergoes a proprietary treatment process to ensure maximum flexural strength.
- The sprues that hold the bar within the block are cut and removed followed by the final hand polish.
- The bar undergoes a final inspection and is fitted onto the physical master model to ensure a passive fit with no rocking and no gaps. (Figure 23)
- Then the bar is tried intraoral in the patient mouth for both groups to ensure the appropriate passive fit for the bar. (Figure 24)
- Then the DTK adhesive is used to cement the bar with TI-BASE abutment.
- The undercut that beneath the bar was block out then the heavy body rubber base impression applied to the patient's custom trays with proper extension and border molding to obtain border registration and the anatomic final impression was taken using light body elastomeric impression material to obtain a mandibular definitive cast for the new mandibular dentures.
- All components of framework were selected from a menu and placed in the correct position in the form of a spine of points. The width and thickness of any part of every component can be changed at these points.
- The PEEK pattern of the framework was made using rapid prototyping technology to evaluate the fitting of the designed framework intra-orally over the zirconia bar before milling.
- After the fitting of the 3-D printed framework was found satisfactory intra-orally over the bar, it was imported into the milling machine to begin the milling process out of medical grade PEEK dental discs. (Figure 24)
- The PEEK framework was then tried on the ZrO2 bar to check its fitness on the cast and intra-orally. (Figure 25)
- Bite registration was performed for the patient.
- Maxillary and mandibular casts were mounted on a semi adjustable articulator using maxillary face bow for maxillary cast and centric inter-occlusal record for the mandibular one.
- The maxilla-mandibular relationship is then transferred to the articulator and setting up all the artificial teeth was arranged according to Becker Principles of lingualized occlusions using maxillary anatomic teeth opposing modified semi-anatomic teeth by reduction of buccal cusps so, the maxillary palatal cusps are the only contacting cusps. Occlusion was checked on the patient at Try in stage.
- Two Processing of mandibular finished denture was done by making wash out packing and final curing, then addition of heat cured surface sealed soft liner was done by second packing in the relieved areas beneath the bar. (Figure 27)

(Softliner, Promedica GmbH, Neumu ¨nster, Germany)
The final prosthesis is inserted in the patient mouth

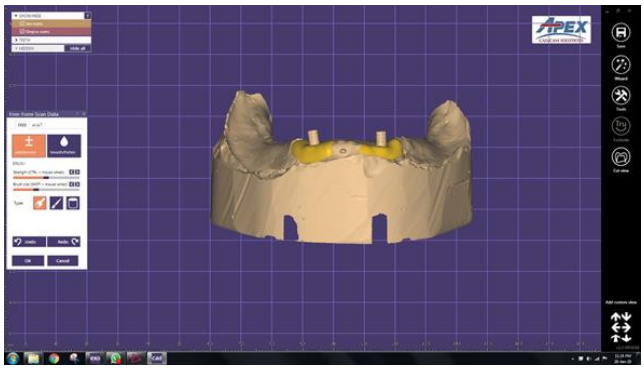

Figure (19): Three dimensional image of the scanned model including the two implant and ti-base abutments

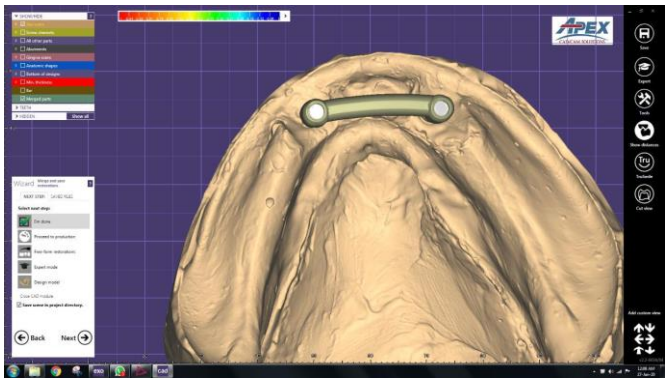

Figure (22): **zinal software design of bar assembly**

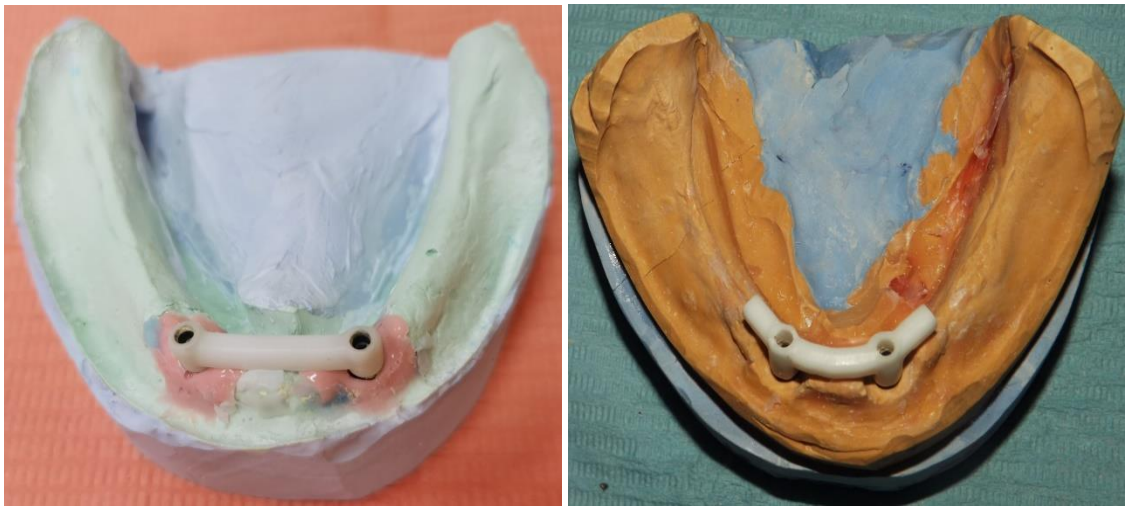

Figure (23): Finished zirconia bar assembly.

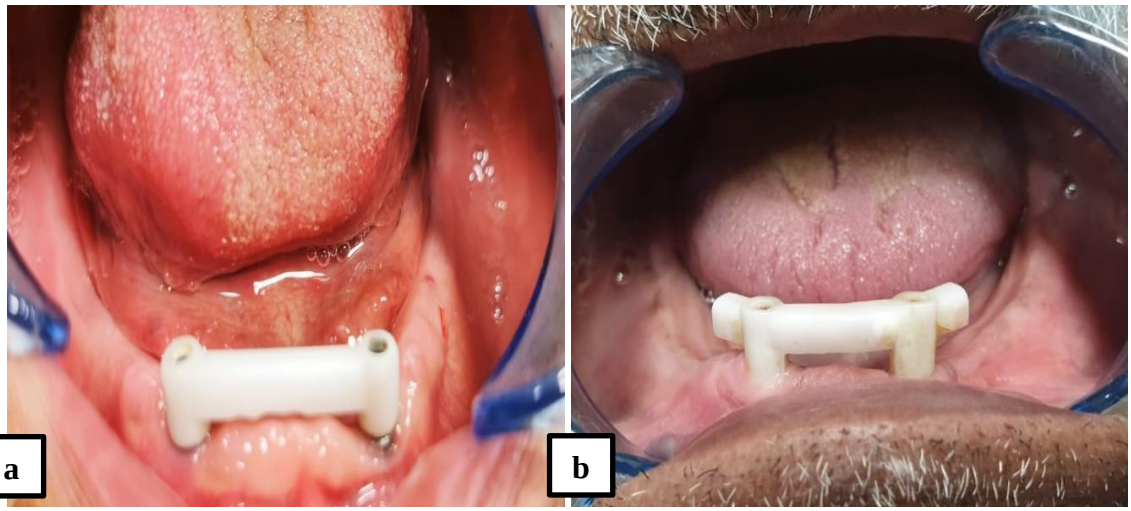

Figure (24): (a)- zirconia bar without cantilever (b)- zirconia bar with cantilever

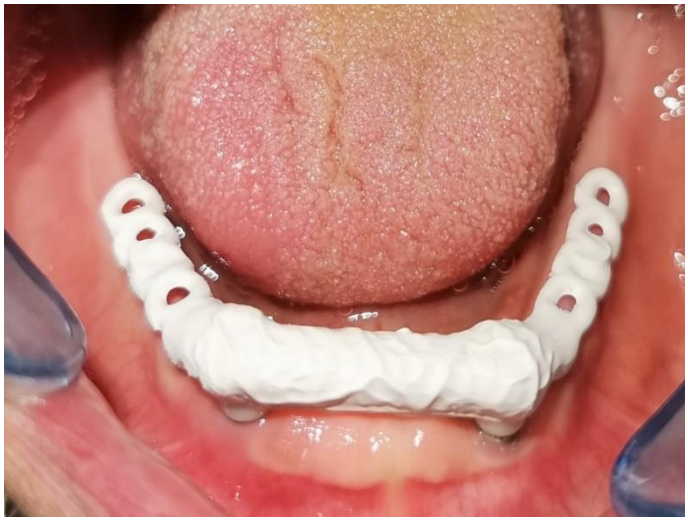

Figure (25): trial of the PEEK framework intraorally.

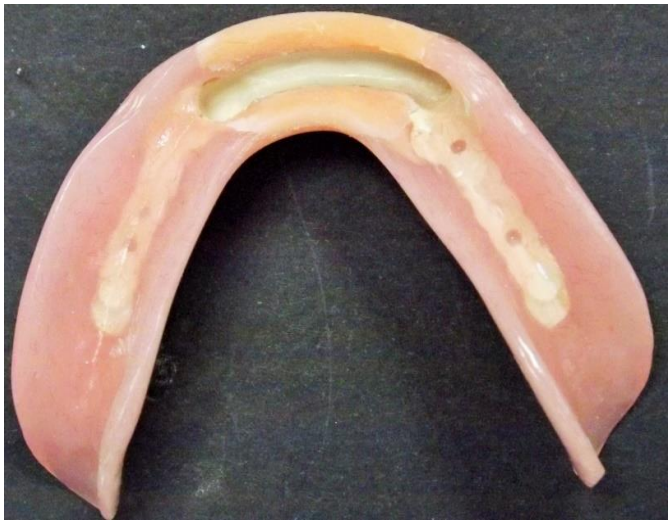

Figure (27): Over-denture fitting surface showing the PEEK framework and soft liner in buccal and lingual surfaces facing the bar.

Evaluation of peri-implant tissue health:

- After mandibular overdenture insertion patients were instructed for overdenture use and preservation of denture hygiene following strict oral hygiene measures.
- Evaluation of peri-implant tissue health was made after insertion (T0), six month (T6) and one year (T12) after overdenture insertion for group I and group II.
- The parameters for peri-implant tissue health evaluation included: bleeding index, gingival index, and peri-implant probing depth.

1. Assessment of gingival index:

-Gingival condition was assessed using modified gingival index according to **Leo & Silness.**(208)

-The scores of gingival index are: Score o: normal gingiva. Score 1: mild inflammation, slight change in color, slight edema, no bleeding on probing. Score 2: moderate inflammation, redness, edema, glazing and bleeding on probing. Score 3: severe inflammation, marked redness and edema, ulceration and tendency to spontaneous bleeding.

2-Assessment of bleeding index*:*

Bleeding on probing was determined according to Mombelli(306), zero=no bleeding, 1=pinpoint bleeding, 2=linear bleeding, 3= profuse bleeding. Fifteen seconds were allowed for bleeding after probing

3. Assessment of peri-implant probing depth:

-The distance between marginal border of the gingiva and the tip of the probe was measured and considered as pocket depth according to **Eickholz et al.**(216)

-Probing depth is measured at four sites (mesial, buccal, distal and lingual) of each implant to the nearest mm by a calibrated plastic periodontal probe [1]to avoid leaving deep scratches in the implant that can serve as reservoirs for inflammation-triggering microbial communities.(226)

Statistical analysis

The data were analyzed using SPSS® software version 25 (SPSS Inc., Chicago, IL, USA). One-Sample Kolmogorov-Smirnov and Shapiro Wilk tests were used to diagnose normality of data distribution of all variables. The data was non-parametric, violate the normal distribution and presented as median (minimum- maximum) for comparison. Freidman test was used to compare data between observation times followed by Wilcoxon signed ranks test for pair-wise comparison between each 2 observation times. Mann Whitney test was used to compare data between groups. P-values <0.05 were considered to be significant.

Results

Peri-implant Soft Tissue Changes

A. Gingival scores

- Descriptive statistics [mean, SD, median, minimum, maximum] of gingival scores at different observation times for groups are shown in table1.
- Comparison of gingival scores between observation times and between groups is presented in table 2 and figure (29).
- Gingival scores significantly increased with advance of time for group I (p<.001) and group II (p=.015).
- Multiple comparisons between each 2 observation times are presented in the same table. For group I, there was a significant difference in gingival scores between T0-T12, between T6-T12. However, there was no significant difference between T0-T6. For group II, there was a significant difference in gingival scores between T0-T6, between T0-T12. However, there was no significant difference between T6-T12
- There was a significant difference in gingival scores between groups at T6 only (p=.045) (table2). No difference in gingival score between groups was noted at T0 and T12.
- Group II showed significant higher gingival scores than group I at T6 (p=.045)

Table 1: Descriptive statistics of gingival scores for both groups at different observation times

Group		T0	T6	T12
Group I (without cantilever)	Mean	.00	.54	.79
	Std. Deviation	.00	.78	.98
	Median	.00	.00	.00
	Minimum	.00	.00	.00
	Maximum	.00	2.00	2.00
Group II (With cantilever)	Mean	.17	.17	.58
	Std. Deviation	.38	.48	.65
	Median	.00	.00	.50
	Minimum	.00	.00	.00
	Maximum	1.00	2.00	2.00

Table 2: Comparison of gingival scores between observation times and between groups

	T 0M (min-max)	T 6M (min-max)	T 12M (min-max)	Freidman test (P value)
Group I (without cantilever)	.00a (.00-2.00)	.00a (.00-1.00)	.00b (.00-2.00)	<.001*
Group II (With cantilever)	.00a (.00-1.00)	.00b (.00-2.00)	.50b (.00-2.00)	.015*
Mann Whitney test (P value)	.050	.045*	.64	

M; median, min; minimum, max; maximum, * p is significant at 5% level. Different letters in the same raw indicates a significant difference between each 2-observation time (Wilcoxon signed ranks test, p<.05)

A. Bleeding scores

- Descriptive statistics [mean, SD, median, minimum, maximum] of bleeding scores at different observation times for groups are shown in table3.
- Comparison of bleeding scores between observation times and between groups is presented in table 4 and figure (30).
- Bleeding scores significantly increased with advance of time for group II only (p=.005). No significant difference in bleeding scores between observation times was noted for group I.
- Multiple comparisons between each 2 observation times are presented in the same table. For group II, there was a significant difference in bleeding scores between T0-T6, between T0-T12. However, there was no significant difference between T6-T12
- There was no significant difference in bleeding scores between groups at different observation times (table2).

Table 3: Descriptive statistics of bleeding scores for both groups at different observation times

group		T0	T6	T12
Group I (without cantilever)	Mean	.00	.04	.13
	Std. Deviation	.00	.20	.34
	Median	.00	.00	.00
	Minimum	.00	.00	.00
	Maximum	.00	1.00	1.00
Group II (With cantilever)	Mean	.00	.17	.33
	Std. Deviation	.00	.38	.48
	Median	.00	.00	.00
	Minimum	.00	.00	.00
	Maximum	.00	1.00	1.00

Table 4: Comparison of bleeding scores between observation times and between groups

	T 0M (min-max)	T 6M (min-max)	T 12M (min-max)	Freidman test (P value)
Group I (without cantilever)	.00a (.00-0.00)	.00a (.00-1.00)	.00a (.00-1.00)	.079
Group II (With cantilever)	.00a (.00-0.00)	.00b (.00-1.00)	.00b (.00-1.00)	.005*
Mann Whitney test (P value)	1.00	.16	.89	

M; median, min; minimum, max; maximum, * p is significant at 5% level. Different letters in the same raw indicates a significant difference between each 2-observation time (Wilcoxon signed ranks test, p<.05)

C. Probing depth

- Descriptive statistics [mean, SD, median, minimum, maximum] of probing depth at different observation times for groups are shown in table5.
- Comparison of probing depth between observation times and between groups is presented in table 6 and figure (31).
- Probing depth significantly increased with advance of time for group I (p<.001) and group II (p<.001).
- Multiple comparison between each 2 observation times are presented in the same table. For group I and group II, there was a significant difference in
-

- pocket depth between T0-T6, T0-T12, between T6-T12.
- There was a significant difference in pocket depth between groups at T12 only (p=.021) (table 6). No difference in pocket depth between groups was noted at T0 and T6.
- Group II showed significant higher pocket depth than group I at T12 (p=.021)

Table 5: Descriptive statistics of probing depth for both groups at different observation times

Group		T0	T6	T12
Group I (without cantilever)	Mean	1.00	1.75	1.46
	Std. Deviation	.42	.75	.51
	Median	1.00	1.50	1.50
	Minimum	.50	1.00	.50
	Maximum	2.00	3.00	2.00
Group II (With cantilever)	Mean	.83	1.50	1.85
	Std. Deviation	.28	.74	.60
	Median	1.00	1.50	2.00
	Minimum	.50	.50	1.00
	Maximum	1.50	3.00	3.00

Table 6: Comparison of probing depth between observation times and between groups

	T 0M (min-max)	T 6M (min-max)	T 12M (min-max)	Freidman test (P value)
Group I (without cantilever)	1.00a (.50-2.00)	1.5b (1.00-3.00)	1.5c (.50-2.00)	<.001*
Group II (With cantilever)	1.00a (.50-1.50)	1.50b (.50-3.00)	2.00c (1.00-3.00)	<.001*
Mann Whitney test (P value)	.16	.37	.021*	

M; median, min; minimum, max; maximum, * p is significant at 5% level. Different letters in the same raw indicates a significant difference between each 2-observation time (Wilcoxon signed ranks test, p<.05)

Discussion

Patients ranged between 55-65 years with main age 60 were selected in this study as the potential of complete edentulism is increased with age, associated with functional and structural functional alterations in the muscles of the stomatognathic system and chewing forces. [(1)].

Patients with Angle's class I maxillomandibular relationship were selected in this study to avoid abnormal forces which might be applied in other maxillo-mandibular relation and affect the implant success. Block et al.,(2) stated that discrepancies in horizontal relationship between the maxillary and mandibular arch can lead to difficulty in developing a harmonious occlusion needed to reduce the stresses of the prosthesis and to avoid overloading the implants.

The patients' systemic conditions were considered in this study. To avoid any metabolic changes that affect post-operative healing and bone remodelling, all uncontrolled diabetic patients were excluded from this study according to Naujokat et al (3) because of high risk of peri-implantitis and increase the level of implant failure. Patients under systemic corticosteroid therapy were also excluded because they may result in compromised osseointegration of dental implants (4). History of bruxism is generally considered a contraindication for dental implants, as implant fracture may be one of the major causes of implant failures. The probable cause of the implant fracture was due to biomechanical overload caused by bruxism (5). Smokers were also excluded from this study because studies have identified a significant risk for implant failure. A present or history of smoking has been identified as a risk factor for peri- implantitis as detected by Becker et al, (6) Degidi et al (7) and de Waal et al.(8).

Construction of complete acrylic dentures for all patient were done using lingualized occlusion scheme, where the maxillary palatal cusps articulate with the mandibular occlusal surfaces in centric, working and non-working mandibular positions. John et al.(9) appear to support the assertions of Lang and Razzoog (10), Geertman etal (11), Kapur etal (12), Boerrigter etal (13), and Wismeijer etal (14) who reported that lingualized occlusion may satisfy the needs of the edentulous patient who has a conventional maxillary denture and mandibular 2-implant overdenture regarding functional and aesthetic needs.

Edentulous patients face problems associated with retention, stability, support, and patient's comfort. [(15)] The use of implants has enabled an increase in the number and versatility of treatments for completely edentulous individuals. [(16)]

In this study, two intra-foraminal implants used to retain mandibular overdenture to take advantage of the excellent bone quality and quantity in this area. [(143)(17)] A conventional protocol for implant placement was advocated because a fully healed ridge ensures implant insertion in a stable ridge dimension and it was also suggested that recent extraction sites should be allowed to heal for four to six months. [(131)] (18) D3 bone type according to Misch bone density classification scheme (350 to 850 Housefield units) were selected for all patients. Bone quality is one reason in implant success at different sites of the mouth. A 12–16% implant

failure rate in D4 bone compared to 4% in types D1 to D3 has been reported [19-22].

In this study, CBCT was used for preoperative planning and evaluation of alveolar bone conditions. As CBCT imaging results in significantly more surgically information in implant dentistry (23). With the aid of CBCT, it became possible to obtain 3-D digital images, thus an accurate assessment of the height and width of alveolar bone available for implant placement. (24). Flapless surgical protocol using stereo-lithographic surgical stent was used in this study. Because flapless surgery leads to better aesthetic outcomes in implants compared with the flap technique (25). In addition, flapless implant surgery leads to less crestal bone loss during the healing period and after loading. However, care should be taken during case selection for flapless implant surgery (26). Flapless implant surgery for edentulous patients has gained popularity (27). An obvious advantage of this technique is the elimination of the need to surgically raise a flap and expose underlying bone to place the implant, the increase patient comfort and acceptance, the decrease of the loss of soft tissues that heal faster with

minimal complications, reduced pain, swelling, reduced surgical procedure time and accelerated recovery (28). The stereolithographic stents have many advantages including minimal invasion, accuracy of implant placement, predictability, less post-surgical discomfort and reduced time required for definitive rehabilitation (29). Accurate positioning of the two implants in their planned sites of the study was important. Three -D computer technology, simulated ideal implant locations are assumed to be transferred intraorally via a stereolithographic surgical guide obtained from CBCT images (30). Stereolithographic guide is reported to have the ability to precisely control implant positions in 3D (30–32). This capability is claimed to make possible flapless surgery (33) and fabrication of provisional or definitive implant dentures prior to implant surgery (34–38).

For all patients enrolled in this study, a standardized implant size to eliminate the effect of implant surface area on the integration process or the implant marginal bone. The selected implant length was 11.5 mm and 3.7 mm in diameter to guarantee rigid bone implant integration. The osteotomy site was done by a low speed hand piece at drilling speed of 1200rpm under irrigation with sterile saline to avoid excessive heat generation which was recommended by Möhlhenrich (39). Proper control of frictional heat generation during preparation of the implants sites was carefully considered for preservation of the surrounding bone cells at the implant sites (40).

Thus using headpieces with low speed, high- torque motor system and a series of sharp drills with a gradual increase in diameter were used along with copious cool sterile saline irrigation during bone preparation of the implant sites to avoid overheating of bone, thermal trauma and ensure sequential widening of the implants bed and initial stability after installation (41). Intermittent drilling was also performed as it allows the saline solution to succeed in the complete length of the bony walls. Additionally, it allows for the escape of bone debris and stop clogging of the cutting

edge of the drills which may decrease the cutting efficiency and eventually increase the heat generation (42). The insertion torque for primary stability of implant placement in this study was 30 N/cm2. It absolutely was agreed that primary stability is key for successful osseointegration.(43) to cut back postsurgical infection; rinsing by chlorhexidine immediately before dental implanting and twice daily for 2 weeks after the surgery was done (44).

Conventional delayed loading protocol was used in this study. Although all three loading protocols provide high survival rates, early and conventional loading protocols are still better documented than immediate loading and seem to result in fewer implant failures during the first year (45). In this study, bar attachment was used to provide distribution of the forces to more implant surfaces, thereby sharing the load. Another primary reason for splinting is to enable the laboratory to compensate for significantly malaligned or poorly positioned implants by fabricating a custom substructure with common path of insertion. (46)

Bar attachments seem to be as suitable as other attachments concerning implant survival rate, improvement of retention and maintenance. (47-49) This design distributes torqueing

forces more favorably to the implants, because of the splinting effect, and enables the clip attachment to rotate around the implants. This action channels the forces to the 2 implants and edentulous areas when the overdenture is subjected to horizontal forces, which are the most damaging for the implants system. (50) In the current study, the use of ZrO2 for the fabrication of a zirconia bar on implants was performed. The potential advantages of ZrO2 compared with Ti, regarding biofilm formation in the oral cavity, has been demonstrated in various studies (51). Zirconia is a promising material for bar fabrication because it can be easily constructed using CAD/CAM and avoid technical errors of conventional casting procedures. PEEK framework was also used as a retentive mechanism for bar that applied to the buccal and lingual surface in direct position with ZrO2 bar. It was concluded that PEEK restorations provide excellent elasticity and resemblance to natural teeth that allows their successful use as restorations over implants. [53] In addition, soft liners were used to obturate the spaces in the denture base around the bar, improve peri-implant tissue health, increase patient satisfaction, reduce costs and minimize soft tissue complications compared to clip attachments [52].

In this study, assessment of peri-implant parameter was done to evaluate peri-implant mucosal conditions around implants to predict long term success of implants. (54) Pressure sensitive plastic probe was used in this study to measure probing depth, gingival index and bleeding index because stainless steel probe may lead to galvanic corrosion and surface scratch that may lead to marginal bone loss (55).

The results of gingival scores revealed a significant increase with time in both groups. This could be attributed to the plaque accumulation and difficulty of cleaning under the bar due to limited access and decreased manual dexterity of old patients. This is in agreement with previous studies which

recorded significantly higher plaque and gingival scores for bar attachment compared to solitary attachments. (56,57)

NO significant difference in gingival scores between group I and group II at T1 and T12, however, gingival scores were significantly higher in group II than group I at T6. The increased inflammation observed in group II after 6 months could be related to difficulty of cleaning and rapid accumulation of plaque around the cantilever arm than non-cantilever bar in the initial period after denture insertion. The extra force exerted upon the cantilever arm after function may also initiate the bone and tissue reaction causing gingival inflammation. This was also supported by the finding that gingival inflammation was not significantly increased in group I between T0-T6, while in group II, there was a significant increase at this interval. (58,59)

Nevertheless, bleeding scores did not increase significantly with time in group I, in contrast to group II that revealed bleeding scores was significantly increased with advance of time. The larger surface of the cantilever bar morphology enhances plaque accumulation and therefore facilitates bleeding which indicate that meticulous oral hygiene are mandatory to ensure the success of cantilever bar attachment. Placement of heat cure soft liner to retain the implant overdenture over the ZrO2 bar may have improved the patient satisfaction and comfort, however, it may have contributed to the increase of gingival and bleeding scores with the advance of time as these soft liners' ingredients may leach out from the material or extrinsic elements may be incorporated into the material. These materials may become rigid and inelastic due to loss of plasticizers, thereby removing the most important characteristic physical property of a resilient denture liner which is the elastic modulus. (60) Therefore, the roughness of the soft liner material will eventually increase and this will in turn render the denture surface a hidden area for microflora and plaque to aggregate. However, on the other hand there was no significant difference in bleeding scores between groups at different observation times. The use of ZrO2 bar could facilitate the cleaning process as it was demonstrated that ZrO2 elicited less plaque accumulation than Ti discs in-vivo (61). However, a superficial bar discoloration was observed after one year which indicate a longer period of follow up is required to evaluate easiness to perform and control good cleansability around the peri implant tissue and the ZrO2 bar over a longer time.

In the current study, pocket depth increased significantly at T6, and continues to increase again at T12 for the 2 groups. Increased gingival inflammation observed with the advance of time in this study could be the reason for the increased pocket depth. Other investigations found that pocket depth increased significantly at T6, however after 1 year the pocket depth then decreased. (62)

The authors of these studies attributed the increased pocket depth to the increased peri-implant bone resorption and peri-implant soft tissue enlargement after 6 months, while the decreased pocket depth after 1 year was attributed to gingival recession. It is worth to mention that these studies mainly investigated solitary attachments such as locators, magnets and telescopic. Gingival hyperplasia in the denture spaces around the bar and abutments was mentions as a cause of increased pocket depth with bar overdenture. (63)

Long term follow up is required because after 3 years Krennmair et al found that pocket depth did not differ between telescopic and milled bar groups (64)

Group II showed significant higher pocket depth than group I at T12. This may indicate that the cantilever bar has promoted the gingival hyperplasia compared to the non-cantilever bar. This significant increase was not observed between groups at T0 and T6.

Despite the significant increase in pocket depth with the advance of time, this was not reflected in vertical bone loss around the implants. The amount of vertical bone loss in the first year (0.6 mm) was less than the normal rate reported in the literature, which is 1.2 mm in the first year. (65,66)

Elsyad et.al.(2016) reported a higher value of vertical bone loss after one year (1.49 mm) of loading of titanium bar-retained implant overdentures using retentive clips. (67)
In the current study, PEEK framework incorporated within the acrylic denture was used as a retentive mechanism over the ZrO2 bar. PEEK possesses high strength, insolubility in common solvents, wear resistance and excellent biocompatibility.(68) with young's modulus and tensile properties close to human bone, enamel and dentin [69].
This combination may have resulted in reduced forces transmitted to the implant and supporting tissues, and therefore reduce the bone loss around the implants. There was no significant difference in vertical bone loss between the two groups after 6 months and one year which is in agreement with a study that found bar-retained implant overdentures with distal cantilevers did not negatively influence the vertical bone loss. (70) However, the overdentures in that study were supported by four implants. Therefore, future clinical trials with a longer observation period and larger number of patients are recommended.
The limitation of this study was insufficient number of patients and the need for prolonged follow up .
The results of the study accept null hypothesis regarding vertical bone loss, and bleeding index between groups while reject null hypothesis regarding probing depth and gingival index

Conclusion

1- Using PEEK framework over mandibular two implant supported zirconium oxide bar without cantilever and without retaining mechanism of the bar in form of clip or sleeve is considered a promising treatment solution.

Using heat cured soft liner in the desired areas beneath the bar maintain good peri-implant results either with or without cantilever extensio